

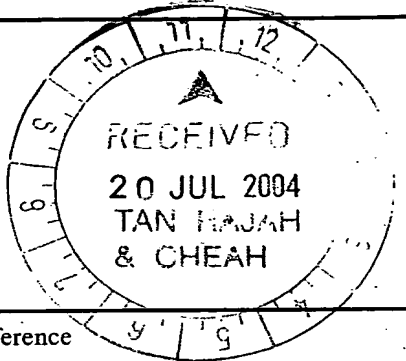
## PATENT COOPERATION TREATY

CONFIRMATION

From the:  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Tan Rajah & Cheah  
9 Battery road #15-00  
Straits Trading Building  
Singapore 049910



**PCT**  
NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY EXAMINATION  
REPORT

**Rec'd PCT/PTO 01 OCT 2004**  
(PCT Rule 71.1)

Date of mailing  
day/month/year

14 JUL 2004

Applicant's or agent's file reference  
ZB/2003/668

**IMPORTANT NOTIFICATION**

International Application No.  
**PCT/SG2003/000067**

International Filing Date  
1 April 2003

Priority Date  
1 April 2002

Applicant

SHEN, Quan PAN

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU

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**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>ZB/2003/668</b>	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No.  <b>PCT/SG2003/000067</b>	International Filing Date (day/month/year)  <b>1 April 2003</b>	Priority Date (day/month/year)  <b>1 April 2002</b>
International Patent Classification (IPC) or national classification and IPC  <b>Int. Cl. <sup>7</sup> C12Q 1/02, 1/68; G01N 33/00</b>		
Applicant  <b>SHEN, Quan PAN</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **4** sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of  sheet(s).

3. This report contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the report
II	<input type="checkbox"/>	Priority
III	<input type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input checked="" type="checkbox"/>	Certain observations on the international application

Date of submission of the demand <b>31 October 2003</b>	Date of completion of the report <b>12 July 2004</b>
Name and mailing address of the IPEA/AU  <b>AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929</b>	Authorized Officer  <b>PHILIPPA WYRDEMAN</b>  Telephone No. (02) 6283 2554

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-27	YES
	Claims None	NO
Inventive step (IS)	Claims None	YES
	Claims 1-27	NO
Industrial applicability (IA)	Claims 1-27	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 - PATIL, J. G. and KHOO, H. W. (1996) "Nuclear Internalization of Foreign DNA by Zebrafish Spermatozoa and Its Enhancement by Electroporation" *The Journal of Experimental Zoology* 274:121-129.

D2 - CHEN, C and CHASIN, L. A. (1998) "Cointegration of DNA Molecules Introduced into Mammalian Cells by Electroporation" *Somatic Cell and Molecular Genetics* 24(4):249-256.

D3 - AINGER, K. et al (1993) "Transport and Localization of Exogenous Myelin Basic Protein mRNA Microinjected into Oligodendrocytes" *The Journal of Cell Biology* 123(2):431-441

Novelty (N) Inventive Step (IS)

D1 discloses the use of in situ hybridisation to visualise exogenous DNA in fixed cells. The citation clearly shows that the location of exogenous DNA can be identified in cells using this method. See in particular figure 6.

D2 also discloses the use of in situ hybridisation to visualise exogenous DNA in cells.

D3 provides a process for monitoring endogenous and exogenous nucleic acids in transit using confocal microscopy and in situ hybridisation.

None of D1 - D3 specifically disclose the use of *in situ* hybridization to monitor nucleic acids in transit. Thus, the claimed invention is considered novel.

The claimed invention lacks inventive step in light to D1 - D3, either taken singly or together. The person skilled in the art (PSA) wanting to follow the "path" of this DNA into cells would recognise that one could carry out each of these procedures in a time course manner rather than waiting until the end of the exogenous DNA uptake process and thus arrive at the claimed invention. Thus, the claims do not contain any inventive step.

Claim 25, directed to a kit for monitoring exogenous nucleic acid in transit, is not considered inventive since it merely recites a series of reagents commonly used in *in situ* hybridization. No invention can be seen in merely gathering and presenting such reagents together.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 21 -24, 26 and 27, are not fully supported by the description because they fail to include all the essential features of the invention. These claims are directed to a process for identifying a cell competent to receive exogenous nucleic acid. However, said process does not define the monitoring of exogenous nucleic acid as provided for by the description and defined as VOID.